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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,305	10/17/2003	Martin P. Vacanti	07917-168001 / UMMC 02-32	8886
23579	7590	05/02/2006	EXAMINER DAVIS, RUTH A	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,305

Applicant(s)

VACANTI ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 23, 26, 27 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22, 24, 25, 28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 18 – 22 and 24 – 33 and species blood (or claims 28) in the reply filed on March 24, 2006 is acknowledged. The traversal is on the ground(s) that there is not a burden on the examiner to search all groups since the groups overlap and are not independent. This is not found persuasive because while the search for the various groups may overlap, an overlapping search is not a coextensive search. Thus a reference that would anticipate one group may not anticipate or even make obvious another group. It is noted that applicant requests a rejoinder upon allowance of the elected claims. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement are subject to being rejoined if they include all the limitations of the allowable product.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 – 17, 23, 26 – 27 and 29 – 32 are withdrawn from consideration as being drawn to non elected subject matter.

It is noted that claim 23 should be included in group II of the election restriction requirement.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 18 – 22, 24 – 25, 28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 5716404).

Applicant claims a living biological matrix comprising a spore like cell, cell fragments, lipids and polysaccharides; a component that adds shape, structure, or support to the matrix; a hydrogel or adhesive; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid. Applicant additionally claims a living biological matrix produced by obtaining a cell sample, disrupting the cell sample to create a mixture of cells and cellular debris, culturing the mixture in a medium such that a biological matrix is formed in vitro, and removing the matrix from the culture medium wherein the cell sample is obtained from a subject who will receive the biological matrix, the cell sample is blood; and the method further comprises adding a component that adds shape, structure or support to the matrix.

Vacanti teaches a biological matrix comprising mesenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and polysaccharides) (abstract, col.2-3), struts (a component that adds shape, structure, support) (col.8-9) and a hydrogel (col.3-4). The matrix further includes cellular components such as

Art Unit: 1651

fibrin, hyaluronic acid, collagen (col.4), fibronectin, laminin or glycosaminoglycans (col.8).

Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.2-3).

Although the reference does not specifically identify that the matrix is “living”, the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the cells are obtained from blood, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

(MPEP 2113)

4. Claims 18 – 19, 21 – 22, 24 – 25, 28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 5885610).

Applicant claims a living biological matrix comprising a spore like cell, cell fragments, lipids and polysaccharides; a component that adds shape, structure, or support to the matrix; an antibiotic; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid. Applicant additionally claims a

Art Unit: 1651

living biological matrix produced by obtaining a cell sample, disrupting the cell sample to create a mixture of cells and cellular debris, culturing the mixture in a medium such that a biological matrix is formed in vitro, and removing the matrix from the culture medium wherein the cell sample is obtained from a subject who will receive the biological matrix, the cell sample is blood; and the method further comprises adding a component that adds shape, structure or support to the matrix.

Vacanti teaches a biological matrix comprising parenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and polysaccharides) (col.2-3), struts (a component that adds shape, structure, support) (col.5), cellular components such as collagen, fibronectin, laminin or glycosaminoglycans (col.5). The matrix further comprises antibiotics (examples). Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.6).

Although the reference does not specifically identify that the matrix is “living”, the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the cells are obtained from blood, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the

Art Unit: 1651

claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

(MPEP 2113)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 28, 2006
AU 1651



RUTH A. DAVIS
PATENT EXAMINER